K130563

# PREMARKET NOTIFICATION

JUN 18 2013

## 510(k) SUMMARY

(As Required By 21 CFR 807.92)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____ Date: MAR 01 2013

**1. Submitter:**

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**2. Name of the Device:**

Trade Name: Full Automatic (NIBP) Blood Pressure Monitor, Model HL858GA
Common Name: Blood Pressure Monitor
Classification Name: Non-invasive Blood Pressure Measurement System
Classification: Class II, 21CFR 870.1130
Classification Panel: 74 Cardiovascular
Product Code: DXN

**3. Information for the 510(k) Cleared Device (Predicate Device):**

A. Full Automatic (NIBP) Blood Pressure Monitor, Model HL868RT, K093831
B. A&D Digital Blood Pressure Monitor, Model UB-512, K042967

**4. Device Description:**

HL858GA uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's arm. All values can be read out in one LCD panel. The device is designed and recommended for use by people over the age of 18 with arm circumference ranging from approx.9 inches to 17 inches (23 cm to 43 cm) and for home use.

The device is equipped with Irregular Heartbeat Detector function which display a symbol or , to indicate the detection of irregular heartbeat rhythm as defined as a rhythm is more than or less than 25% from the average heartbeat intervals during the measurement. Besides, user can save and manage the measurement data by transferring the measured readings of blood pressure to the connected personal computer (PC) via USB cable. Additionally, the Risk Category Indicator (Six Levels) feature will classify the blood pressure results with WHO (World Health Organization) Classifications, which are Sever Hypertension, Moderate Hypertension, Mild Hypertension, High Normal, Normal, and Optimal. The Corresponding LCD segment will be turned on along with the systolic, diastolic, and heart rate information.

**5. Intended Use**

HL858GA uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's arm. All values can be read out in one LCD panel. The device is designed and recommended for use by people over the age of 18 with arm circumference ranging from approx.9 inches to 17 inches (23 cm to 43 cm) and for home use.

**6. Comparison of device to predicate device:**

**Product Specification Comparison Table of Subject device HL858GA and predicate device HL868RT (K093831)**

| Item | Predicate device HL868RT (K093831) | Subject device HL858GA |
|---|---|---|
| **Method of measurement** | Oscillimetric | Same as left |
| **Range of Measurement** | Pressure 0~300mmHg<br>Pulse 40-199 beats/minute | Same as left |
| **Accuracy** | Pressure +/− 3mmHg<br>Pulse +/− 5% | Same as left |
| **Inflation** | Automatic inflation<br>(Air pump) | Same as left |
| **Deflation** | Automatic air release control valve | Same as left |
| **Exhaust** | Automatic exhaust valve | Same as left |
| **Display** | Liquid Crystal Display | Same as left |
| **Power Supply** | AA(1.5V)alkaline battery × 4<br>or 6V AC adapter (optional) | AA(1.5V)alkaline battery × 4 |
| **Storage/ Transportation** | - 20℃ ~ + 70℃<br>(- 4°F~ +158°F), | - 25℃ ~ + 70℃<br>(- 13°F~ +158°F), |

| Environment | ≦ 90% R.H. | ≦ 93% R.H. |
|---|---|---|
| **Operating Environment** | 10℃ ~40℃ (50°F~104°F), 15% ~ 90% R.H. | 5℃ ~40℃ (41°F~104°F), 15% ~ 93% R.H. |
| **Material** | ABS housing and rubber keys | ABS housing and ABS keys |
| **Sets of memory** | 2×60, total 120 | 3×40,total 120 |
| **Number of Push Button** | 7 | 4 |
| **Storage pouch** | Yes | Same as left |
| **Cuff size** | Arm circumference approx. 23~43cm (9~17 inches) | Same as left |
| **Unit Weight** | 10.33 ± 0.35oz (293±10g) (Batteries Excluded) | 8.73 ± 0.35 oz (247.5 ± 10 g) (Cuff and Batteries Excluded) |

**Changes from the predicate device HL868RT (K093831):**

*Changing of numbers of push buttons, push buttons' material and positions.

* Additional modified feature of Risk Category Indicator (Six Levels)

For the modified feature of Risk Category Indicator (six levels) was compared with the other predicate device A&D UB-512 (K043217).

**7. Discussion of Clinical Tests Performed:**

Subject device HL858GA is compliant to the ANSI/AAMI SP10:2002/(R)2008 & ANSI/AAMI SP10:2002 /A1:2003/(R)2008 & ANSI/AAMI SP10:2002/ A2:2006/(R)2008 Manual, electronic or automated sphygmomanometers. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

**8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The subject device was tested to evaluate its safety and effectiveness, including the followings:

a. **Safety Test**:

-IEC 60601-1:2005, Medical electrical equipment - Part 1: General Requirements for basic safety, and essential performance

-IEC 60601-1-11:2010, Medical electrical equipment-Part 1-11 :General Requirement for basic safety and essential performance- Collateral Standard :Requirements for medical electrical systems used in the home healthcare environment.

**b. EMC Test**: IEC 60601-1-2 Edition 3:2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

**c.FCC Test:** FCC 47 CFR Part 15, Subpart B

**d. Biocompatibility Test**:

- ISO 10993-1:2009, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5:2009, Biological evaluation of medical devices -Part 5: Tests for In Vitro cytotoxicity.
- ISO 10993-10:2010,Third Edition Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

**e. Reliability Test:** ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/(R) 2008 & ANSI/AAMI SP10:2002/A2:2006/(R) 2008, Manual, electronic or automated sphygmomanometers.

**f. Risk Assessment:** ISO 14971:2007 Second Edition, Medical devices -Application of risk management to medical devices

**9. Conclusions:**

The subject device was tested and fulfilled the requirements from those standards mentioned above, and it's concluded that the subject device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-002

June 18, 2013

Health & Life Co., Ltd.
Sarah Su
9f, No.186, Jian Yi Road
Zhonghe District, New Taipei City, 23553 TW

Re: K130563
Trade/Device Name: Full automatic (nibp) blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Blood Pressure Monitor
Regulatory Class: Class II
Product Code: DXN
Dated: May 14, 2013
Received: May 20, 2013

Dear Sarah Su:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indication for Use

**510(k) Number (if known):** K130563

**Device Name:** Full Automatic (NIBP) Blood Pressure Monitor, Model HL858GA

**Indications for Use:**

HL858GA uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate. The measurement position is at human being's arm. All values can be read out in one LCD panel. The device is designed and recommended for use by people over the age of 18 with arm circumference ranging from approx.9 inches to 17 inches (23 cm to 43 cm) and for home use.

When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings. And this device can let the memory data be transferred to the connected personal computer (PC) via USB cable.

Besides, Risk Category Indicator (Six Levels) feature will judge blood pressure results into six levels based on WHO (World Health Organization) classification with corresponding bar segment on the edge of screen.

| Prescription Use _____ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use __V__ (21 CFR 801 Subpart C) |
|---|---|---|

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Concurrence of CDRH, Office of Devices Evaluation (ODE)



Owen P. Faris -S
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